

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:)	
)	Group Art Unit: 3739
Huy D. Phan)	
)	Confirmation No.: 7042
Serial No.: 10/660,822)	
)	Examiner: Gibson, Roy Dean
Filed: September 12, 2003)	
)	
For: VACUUM-BASED CATHETER)	
STABILIZER)	

DECLARATION OF MICHAEL J. BOLAN UNDER 35 U.S.C. §1.131

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Michael J. Bolan, hereby declare as follows:

1. I am employed with Vista IP Law Group LLP, and am the patent attorney who is prosecuting the above-identified application.
2. I located an invention disclosure form, entitled "Ablation of Cardiac Arrhythmias from the Pericardial Space," within the prosecution file of the above-identified patent application (pertinent portions of which have been attached hereto as Exhibit A). The invention disclosure form clearly shows the distal end of an ablation, which comprises a shroud, vacuum ports, and a thermocouple for sensing temperature that are arranged in the manner required by claims 29, 30, and 34. As evidenced by the invention disclosure form, the inventions of claims 29, 30, and 34 were conceived on

December 18, 2001, which is prior to June 14, 2002 (the earliest effective filing date that U.S. Patent Application Ser. No. 10/425,251 would be entitled to).

3. I also located a letter from Albert K. Kau, in-house patent counsel for Scimed Life Systems, which evidences that the invention disclosure form was transmitted on February 6, 2003, to Dave T. Burse, outside patent counsel then employed at Bingham McCutchen LLP.
4. All statements made herein of my own knowledge and true and all statements made on information and belief to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: September 26, 2007


Michael J. Bolan

EXHIBIT A

INVENTION DISCLOSURE

LONG FORM

PR#: 02-D0252

Earliest Written Documentation of Invention: 12/18/01

Title of Invention: **Ablation of Cardiac Arrhythmias from the Pericardial Space**

Key Words: Epicardial Ablation, Ground Catheter, Afib, VT, Minimally Invasive Procedure, Pericardial Space Access.

Signed Inventor(s):

Name

Address

1.

Huy Phan

(Print/Type Name)


(Signature)

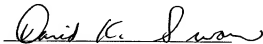
966 Ketch Place
San Jose, CA. 95133

2.

(Print/Type Name)

(Signature)

Witnessed:



1-8-02

David K. Swanson
Print

Date



1-8-02

Robert F. Bencini
Print

Date

I. General Information

Documentation of Idea:

- a. Date of first known disclosure: 12/18/01
- b. To whom: Allan Salas
- c. Date of first drawings: 12/18/01
- d. Who has custody of drawings? Huy Phan

Test of Invention:

Numerous testing has been conducted whereby a ground catheter was placed underneath the half-submerged piece of bovine heart and a balloon made of regenerated cellulose was placed on top. The prototype device was connected to the EPT-1000 XP generator and setting was for 150 Watt, 120 seconds, and temperature of 80 degree C and the flow-rate was 8ml/min using a syringe pump. The lesion was thick, up in the range of 1.2 – 1.7 cm in tissue depth and transmurally.

Disclosure outside of EPT.

- a. Has the invention been disclosed outside of EPT by written or oral communication? NO
- b. If so, to whom?
- c. By whom?

Know related publications, patents, or patent applications:

EPT Microporous Patent 6454766 and Ground Catheter Patent W002270064.

II. Description of Invention

Products Affected:

Chilli Catheter, Irrigation Catheter, Ground Catheter, Balloon Ablation Catheter, Basket Constellation Catheter.

What problems are solved by the invention? (What are the advantages?)

(Disease of VT and AFib)

(Advantage of Minimally Invasive Procedure)

The current device to treat VT is cooled tip ablation such as the Chilli Catheter or the Irrigated tip catheter to produce deep lesion. Because the Ventricle tissue is thick, it's difficult to achieve transmural lesion with current treatment. Other includes surgical treatment, which required an opened heart procedure and the use of heart lung machine.

Briefly describe prior art, and the disadvantages of other known approaches.

1. The current device to treat VT is cooled tip ablation such as the Chilli Catheter or the Irrigated tip catheter to produce deep lesion. One of the disadvantage of the current procedure of using the ground pads is the dispersing of RF energy throughout the body. Much of the RF energy is lost through the body and the blood pool. Because the Ventricle tissue is thick, it's difficult to achieve transmural lesion with current treatment.
2. Other includes surgical treatment, which required an opened heart procedure and the use of heart lung machine.
3. Other includes the ICD devices which are expensive, device complication of battery operated. and not a permanent cure for the disease.
4. Drug for treatment of VT or Afib can have many side-effects and only for temporary treatment, thus not a cure.

Describe what is new or novel in the invention.

1. The use of a stabilizing device such as suction to maintain tissue contact on a beating heart.
2. The use of a balloon or microporous ablation device for deep tissue ablation with multiple temperature control sensing devices.
3. The use of an internal ground catheter to maximize the energy delivered to the tissue and to provide a direct current path to achieve transmural lesion.
4. The use of a minimally invasive procedure such as sub-xiphoid, intercostal space, or MidCab procedure to access the heart via pericardial space.
5. The use of camera and light for direct visualization.
6. Capable of using the internal ground catheter with Chilli or Blazer to ablation between chambers such as the ventricular his bundle.

Brief Description of Invention:

The invention was to create an ablation device to treat arrhythmias such as VT or Post-MI Afib, SVT and Flutter, epicardially via a trocar from the pericardial space. The ablation structure is composed of microporous or hydroscopic polymer that can carry the Radio Frequency energy from the electrode inside the balloon to the interface of the tissue. The ablation structure is enclosed by a suction device that assisted in stabilizing the cardiac tissue and ablation structure, while the heart continues to beat.

The internal return or ground catheter will be accessed percutaneously from the femoral vein or sub-jugular vein to the atria or ventricular chamber. This catheter consisted of one or multiple coils and acts as a return catheter to complete the RF circuit. By placing the return catheter inside the heart, the path of the current delivered by the ablation device will be shorter, crossing the wall of the heart to produce an efficient and transmural lesion.

Detailed Description of Invention:

1. The cannulae in this invention utilized the single or multiple lumen design. One of the inventions here is that the cannulae capable of carrying a light source such as a fiber optic light, a lumen for camera, and a lumen for the mapping or ablation catheter. Other can be a dual lumen cannulae that can accommodate existing camera from company such as Stryker Endoscopic and the other lumen to carry the mapping or ablation catheter. The cannulae can have different configurations such as length, distal bend angle, OD and ID, number of lumen, and the cannulae material property such as polymer or steel. Inside this lumen

can be a liner made out of Teflon, PEEK, Polyimide, Nylon, Polyethylene, or other lubricious polymer linings. SEE DRAWINGS OF CANNULAE

Once the cannulae is in desire position, the ablation catheter can be introduced via the lumen in the cannulae. One of the requirements for the ablation catheter is that it must be low profile when introduced through the cannulae and then expand into a balloon ablation device with suction capability, attaching itself to the epicardial anatomic contour.

2. The first design of such ablation devices is the conical ablation configuration which consisted of 2 to 12 suction holes surrounding the outside of the ablation structure. Temperature sensors will be located on the outside and inside of the ablation device as a feedback mechanism to determine the appropriate amount of RF energy delivered to the tissue. The suction device can me made out of silicone rubber or polyurethane polymer. By enclosed the ablation structure inside the suction structure, the ablation structure is masked from inadvertent ablation of the lungs, esophagus, or other peripheral structures. The ablation structure can be a microporous balloon (See Microporous Balloon Patents), Chilli Catheter, or Irrigation Catheter. Microporous or Hydroscopic Balloon is the prefer choice for VT ablation or Afib ablation. SEE DRAWINGS OF CONICAL ABLATION STRUCTURES.

3. The ground catheter is designed to access percutaneously via the femoral or jugular vein to the atria or ventricular chamber. The ground device can be a steerable or non-steerable catheter which is introduced through an introducer sheath of 9fr – 14 fr and made of 1-4 electrode over a polymer shaft. Covering the electrodes is a slit polymer sheath used to protect the electrode from direct contact with the tissue for unwanted ablation. The ground catheter is preferably resided on the target tissue or in the blood pool. SEE DRAWINGS OF GROUND CATHETER. Also see patent # W002270064.

VIDEO ASSISTED THOROSCOPIC SURGERY OF VENTRICULAR TACHYCARDIA MAPPING & ABLATION

Purpose: To create a novel methodology in treating VT via a port access.

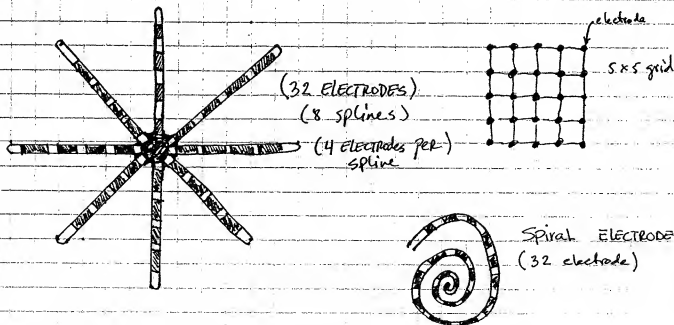
BACKGROUND: Current treatment of VT or VT post-MI is either conventional open heart surgery or Defibrillator.

Conventional heart surgery: Invasive, Removal of Infarction tissue, High risk of Mortality, & by pass require.

Defibrillator: Expensive, not a cure, Device complication.

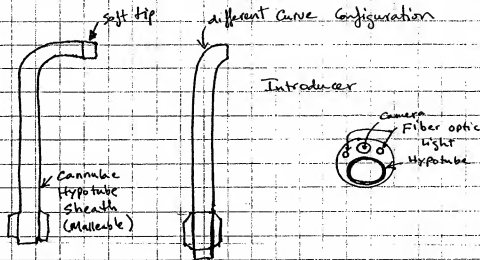
Novel Ideas & Methodology:

1. Epicardial mapping (high density electrodes) via port incision or subxiphoid.



VATS OF VT MAPPING & ABLATION

Page No. _____



2. Suction and Ablation.

- Ability to provide suction to stabilize the ablation electrode from moving out of position.
- Pull/suck in the ventricular epicardial tissue toward the ablation electrode.
- Suction covering provide protection/shielding the ablation electrode from adjacent tissue such as epicardial vessels, lungs, esophagus.
- Wet technology provide deep ablation when combining with internal ground electrode. Capable of creating up to 2.0 cm in vitro. 1.0 cm — 2.0 cm lesion depth.
 - Micro porous
 - Hydroflouro (HF)
 - Tecophilic (polyurethane)
- Temperature sensing outside of balloon.
- collapsible balloon and suction devices to go through a cannulae.

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Inspected & Understood by me, Na Na

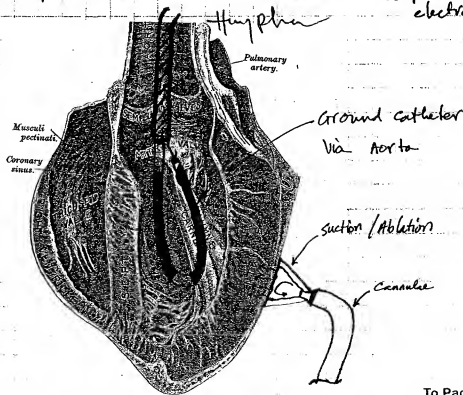
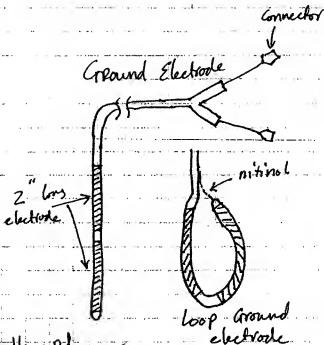
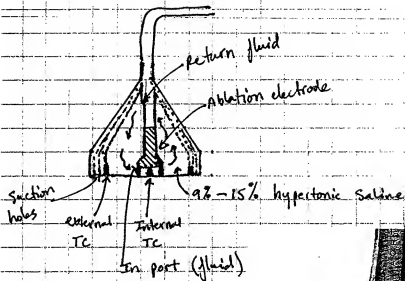
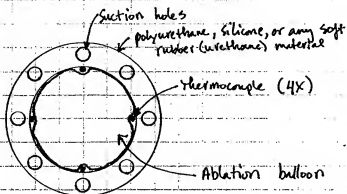
Date

Invented by Hy Ph

Date

12/18/01

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Date

12/19/01

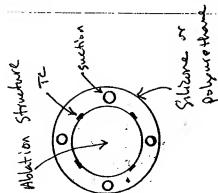
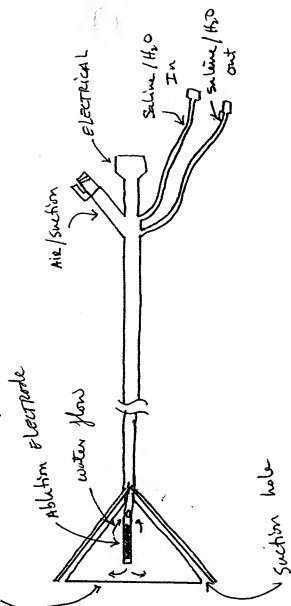
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Hyp phn

Date

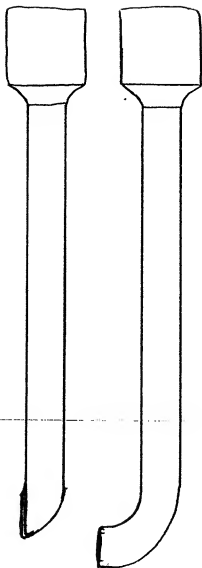
12/18/01

Regenerate Cellulose / Tescophilic Membrane



Hy plw 11/04/02

Cannulae



try for 11/4/02

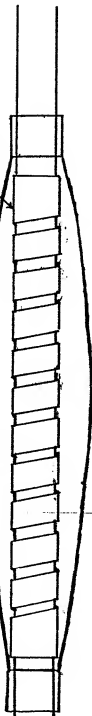
Ground

Catheter

with Protector.

polymer strut to prevent ground can't from
contact with tissue.

ground catheter



thy pl
10/8/02



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One Scimed Place
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612.494.1700
www.bsa.com

February 6, 2003

David T. Burse, Esq.
Bingham McCutchen LLP
1900 University Avenue
East Palo Alto, CA 94303

RE: **Coronary Sinus Reference/Ground Catheter**
Our File No. 03-035
Invention Disclosure Nos. 02-D0252 and 02-D0988

Dear Dave:

Enclosed please find Invention Disclosure Nos. 02-D0252 and 02-D0988. The inventors are Josef Koblish, Huy Phan and David McGee. Please call me if you have any questions regarding the invention.

I would like to receive a draft by April 7, 2003.

Sincerely,

A handwritten signature in black ink, appearing to read "Albert K. Kau".

Albert K. Kau
Patent Counsel

AKK:bkh

Enclosure